

Application Number 10/698,881
Response to Office Action mailed September 13, 2007

REMARKS

This Amendment is responsive to the Office Action dated September 13, 2007.

Applicants have amended claims 28, 29 and 41 for clarity reasons unrelated to patentability.

Applicants have canceled claims 1, 4-11, 23, 25, 27, 30-32 and 38-40, and added new claim 43.

Claims 2-3, 12-17, 23 and 26 were previously canceled.

Claims 19-22, 28-29, 33-37 and 41-43 are now pending. Claims 19, 28, 33 and 41 are the pending independent claims.

Double Patenting Rejections

In the Office Action, the Examiner advanced provisional non-statutory obviousness-type double patenting rejections with respect to several of the claims. Applicants note the provisional status of such rejections.

Applicants also note that the current claim cancellations should render all of the provisional double patenting rejections moot.

Claim 41 was included in the double patenting rejections. However, Applicants believe that this was a mistake, as claim 41 includes features similar to claims 19, 28 and 33, which were not included in the double patenting rejections.

Claim Rejections Under 35 U.S.C. § 102

In the interest of expediting prosecution of the Application, Applicants have canceled all pending claims that were rejected under 35 U.S.C. 102. However, Applicants do not acquiesce to any of the rejections or the Examiner's interpretations of the prior art.

Claim Rejections Under 35 U.S.C. § 103 – Independent claims 19, 28, 33 and 41

The pending claims stand rejected as being unpatentable under 35 U.S.C. § 103 based on several different rationales. In particular, the Examiner advanced the following rejections of independent claims 19, 28, 33 and 41.

Independent method claims 19 and 33 were rejected under 35 U.S.C. § 103 as being unpatentable over Krakovsky '840 (US Patent 5,454,840) in view of Whitehurst '294 (US Patent

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6,901,294) or in view of Brenman '102 (US Patent 4,663,102) and further in view of Mann '171 (US 6,941,171).

Independent device claims 28 and 41 were rejected under 35 U.S.C. § 103 as being unpatentable over Krakovsky '840.

Independent claims 19 and 41 were rejected under 35 U.S.C. § 103 as being unpatentable over Whitehurst' 895 (US Patent 6,885,895) in view of Mann '171 or as being unpatentable over Whitehurst '895 in view of Whitehurst '294 and further in view of Mann '171 and still further in view of Krakovsky '840.

Independent claims 28 and 41 were also rejected under 35 U.S.C. § 103 as being unpatentable over Gerber '240 (US Patent Application 2004/0049240) in view of Krakovsky '840.

Independent claims 19 and 33 were also rejected under 35 U.S.C. § 103 as being unpatentable over Gerber '240 in view of Mann '171, or as being unpatentable over Gerber '240 in view of Krakovsky '840 and further in view of Mann '171.

Applicants respectfully submit that all of these rejections (as applied to independent claims 19, 28, 33 and 41) are improper for at least two reasons. In the following discussion, Applicants provide a brief summary of the currently pending claims, and detailed explanations of the two fundamental problems that pervade the Examiner's entire analysis of claims 19, 28, 33 and 41. Applicants believe that the two fundamental points discussed below address and overcome all pending rejections.

In general, Applicants have cancelled claims as indicated above to specifically focus the prosecution of the present application on claims that require the delivery of a training sequence of stimulation pulses to a prostate gland via an implantable medical device. Claims 19-22 and 33-37 recite methods and claims 28-29 and 41-43 recite implantable medical devices that perform such methods. All pending claims now require delivery of a training sequence to the prostate gland that defines a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week. Claim 33 further requires that the first pulse train is different than the second pulse train, and claims 19, 33 and 41 more specifically require that the second pulse train includes more pulses per unit time than the first pulse train.

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Nothing in the applied prior art discloses or suggests such features. Furthermore, Applicants respectfully submit that the Examiner's analysis of the different claims includes at least two fundamental problems. First, the Examiner erred in concluding that the Mann '171 reference (which discloses the stimulation of nerve pathways of the bladder) would have led a person of ordinary skill in the art to provide a training sequence of stimulation pulses to a prostate gland to change the fibrous structure of the prostate gland.

Second, the Examiner erred in concluding that the Krakovsky '840 reference (or any of the applied prior art) suggests a training sequence that defines a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week. More specifically, with regard to this second point, the Examiner erred in concluding that pulse trains on the order of a week (which the Examiner acknowledges as being lacking from Krakovsky '840) are akin to optimizing a result effective variable, and would have been obvious for this reason.

With regard to the first point, the Examiner recognized that the various primary references (such as Krakovsky '840, Whitehurst '294 and Brenman '102) lack any suggestion of the use of stimulation pulses to train the prostate gland to become more compliant, i.e., relax its fiber structure. However, the Examiner argued that Mann '171 teaches stimulation of nerve pathways of the bladder that diminishes involuntary bladder contractions. Based on this, the Examiner argued that it would have been obvious to have simulated the prostate gland with a training sequence in order to change the fibrous structure of the prostate gland.

Applicants respectfully disagree with the Examiner's conclusion. A person of ordinary skill in the art would not have considered the stimulation of nerve pathways of the bladder (per Mann '171) to have been relevant or applicable to prostate gland stimulation. The bladder and the prostate gland are entirely different organs of the body. Moreover, the teaching of Mann '171 appears to be motivated to facilitate *increases* to bladder volume, which is not the goal of Applicant's invention or the therapeutic result of the claimed techniques. Indeed, Applicant's claimed techniques do not purport to *increase* the volume of the prostate gland, as this would appear to complicate BHP symptoms.

In general, any notion that a person of ordinary skill in the art would have been motivated to train the prostate gland to become more compliant based on a teaching of Mann '171 is totally

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flawed. Mann '171 does not even concern any stimulation of the prostate gland. Moreover, although the Examiner stated that Mann '171 teaches stimulation of the bladder to make the bladder more compliant, the Examiner actually identified nothing in Mann '171 that suggests a desire to make the bladder more compliant via a training sequence of stimulation pulses. Instead, Mann '171 specifically teaches a system and method to reduce or eliminate the incidence of unintentional episodes of bladder emptying by stimulating nerve pathways that diminish involuntary bladder contractions, improve closure of the bladder outlet, and/or improve long-term health of the urinary system by increasing bladder capacity and the period between emptying.

The Examiner identified nothing in Mann '171 that even suggests that bladder capacity is increased specifically by the bladder being trained via stimulation pulses to become more compliant. Furthermore, even if Mann '171 suggested such features, this would not have led a person of ordinary skill in the art to apply such training sequences to the prostate gland to change the fibrous structure of the prostate gland. Any general teaching that training sequences of stimulation pulses may be applied to one organ of the body for one purpose would not have lead a person of ordinary skill in the art to use training sequences of stimulation pulses on other organs for entirely different purposes.

In short, Applicants' first point is that a person of ordinary skill in the art would not have considered the stimulation of nerve pathways of the bladder (per Mann '171) to have been relevant or applicable to prostate gland stimulation. The bladder and the prostate gland are entirely different organs of the body, and the teaching of Mann '171 appears to be motivated to *increase* the volume of the bladder. Applicant's claimed technique does not purport to *increase* the volume of the prostate gland, as this would appear to complicate BHP symptoms.

With regard to the Applicants' second point, Applicants submit that nothing in the applied prior art even remotely suggests the delivery of training sequences of pulses to the prostate gland via electrodes disposed on or implanted within the cellular muscular tissue of the prostate gland. Again, all pending claims recite the delivery of a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week, and wherein the second pulse train is different than the first pulse train. Nothing in the applied prior art even remotely suggests such features.

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For these features of Applicants claims (i.e., delivery of a first pulse train and a second pulse train wherein the second pulse train includes more pulses per unit time than the first pulse train), the Examiner has cited Krakovsky '840. Krakovsky '840, however, has nothing to do with the delivery of training sequences of pulses that change the fibrous structure. Instead, Krakovsky '840 discloses the delivery of stimulation pulses over the course of a sexual encounter that lasts 5-20 minutes.

The Examiner recognized that none of the applied references suggests the delivery of first and second pulse trains that last on the order of one week. However, the Examiner argued that the period associated with the delivery of a pulse train is a "result effective variable," and that a person of ordinary skill in the art would have been motivated to modify the period associated with such sequences of Krakovsky '840 (which last a couple minutes or less) to define sequences that last on the order of a week.

In response, Applicants respectfully submit that the Examiner's argument is flawed insofar as the "result" that is achieved according to the teaching of Krakovsky '840 is erection, emission and ejaculation over the course of a sexual encounter. Therefore, any notion that a person of ordinary skill in the art would have modified these sequences of Krakovsky '840 to last on the order of a week is incorrect, as no sexual encounter lasts even remotely that long. Furthermore, any notion that a person of ordinary skill in the art would have used sequences of Krakovsky '840 (designed for sexual encounters) to provide for prostate treatment to make the prostate gland more compliant is nothing more than conjecture.

In the Office Action, the Examiner stated that "it has been firmly established in the case law that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges of a 'result effective variable' involves only routine skill in the art." In this case, however, the Examiner has not demonstrated that the period associated with the delivery of a pulse train is a "result effective variable" as defined by Applicants claims. In particular, the Examiner has identified nothing in the prior art that would have suggested that the lengths of time associated with two different pulse trains would effect the result of prostate gland therapy. On the contrary, as noted above, the "result" desired in Krakovsky '840 is erection followed by emission and then ejaculation. Accordingly, person of ordinary skill in the art would

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have considered pulse sequences that last on the order of a week to be ineffective for the "result" desired in Krakovsky '840, i.e., erection, emission and ejaculation

Even if the cases cited by the Examiner are legitimate law¹, the Examiner has not even attempted to address whether this law is applicable to the present case insofar as the Examiner has not even attempted to show that the prior art recognizes the period associated with the delivery of a pulse train as a result effective variable. Furthermore, Applicants claims are concerned with the result of changing the fibrous structure of the prostate gland, whereas the desired result in Krakovsky '840 is erection, emission and ejaculation over the course of one sexual encounter.

In line with the case law relied upon by the Examiner², it is well-established that a particular parameter must first be recognized as a result-effective variable, i.e., a variable that achieves a recognized result, before any determination of optimization might be characterized as routine experimentation. The applied prior art makes no mention of training sequences, much less teaches that time periods for the first and second pulse trains are result-effective variables that can affect training results to the prostate gland. Instead, desired result in Krakovsky '840 is erection, emission and ejaculation over the course of a sexual encounter. The Examiner's statement that training sequences of first and second pulse trains on the order of a week are "result effective variables" finds absolutely no support from the evidentiary record. No reasonable interpretation of the prior art would lead to a conclusion that a person of ordinary skill in the art would modify the teaching of Krakovsky '840 to provide pulse trains that last on the order of a week, as no sexual encounter lasts this long.

Contrary to the Examiner's conclusions, nothing in any of the applied prior art teaches or suggests that the timing of any training sequence is result effective. Indeed, the applied prior art does not even teach the use of training sequences for prostate gland simulation, much less provide any suggestion that the timing of sequences can effect the result of changing the fibrous structure of the prostate gland. Again, the Examiner's statement that training sequences of first and second pulse trains on the order of a week are result effective variables finds absolutely no support from the evidentiary record and appears to be the Examiner's conjecture. The pulses

¹ *In re Alter* and *In re Boesch* are both cases handed down prior to the creation of the Federal Circuit.

² *In re Alter* and *In re Boesch*.

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provided by Krakovsky '840 over a 5-20 minute sexual encounter would never be extended to last on the order of a week. Indeed, a person of ordinary skill in the art would have consciously avoided the modifications to Krakovsky '840 that are proposed by the Examiner, lest the device of Krakovsky '840 would have become ineffective for its intended purpose.

In responding to Applicant's arguments with respect to the "result effective variable," the Examiner cited column 3, lines 36-46 of Krakavsky '840, and argued that this section of Krakavsky '840 states that any of pulse height, pulse width, frequency, duration and sequence can be reprogrammed for each individual patient. This teaching of Krakavsky '840, however, would not have led any person of ordinary skill to define sequences that last on the order of a week, as sequences that last on the order of a week would amount to an unreasonably long sexual encounter that no person would desire and no physician would program into a medical device.

Accordingly, the problem with the Examiner's conclusion is that the result desired by Krakavsky '840 (a successful sexual encounter) is different than the result desired by Applicant's invention (training the prostate gland to change its fibrous structure). To the extent that the Examiner's analysis of "result effective variables" could be valid, the optimization of the variable must still achieve the desired result of Krakavsky '840. In this case, if the device of Krakavsky '840 were modified to use pulse sequences that lasted on the order of a week, this would not achieve the desired result of Krakavsky '840. Therefore, the Examiner's reliance on an analysis of "result effective variables" is flawed, and is insufficient to meet the Examiner's evidentiary burden of proof to establish obviousness.

As a final point, Applicants note that the Examiner distinguished between the method claims and the device claims. In particular, for the device claims, the Examiner gave less patentable weight to the requirements of prostate gland stimulation, noting that the prior devices may anticipate the device claims if they are inherently capable of stimulating the prostate gland in the manner claimed.

Applicants submit, however, that the arguments above with respect to the Krakovsky '840 reference demonstrate that the device of Krakovsky '840 is not inherently capable of providing sequences of pulses to the prostate gland that last on the order of a week. Again, the pulses provided by Krakovsky '840 last over a 5-20 minute sexual encounter, and would never be extended to last on the order of a week, or the device of Krakovsky '840 would have become